

**REMARKS**

Claims 1-15 are pending in this action. The Examiner has rejected claims 1-9 and 11-15. The Examiner has objected to, but not rejected, claim 10.

**1. Amendments to the Claims:**

Claims 2, 13, and 14 have been cancelled.

Claim 1 has been amended to recite a method of treatment. Support is found in the Specification, page 1, lines 7-10.

Claims 1, 8, and 11 have been amended to incorporate claim 2 and to remove the “including” language to better conform with U.S. patent practice.

Claims 3-7, and 15 have been amended to recite “the method” to be consistent with claim 1.

Claim 7 has been amended to add commas, for grammatical purposes.

Claim 9 has been amended to better conform with U.S. patent practice.

Claim 10 has been amended to be independent, and to add commas and a spaces for grammatical purposes and to clarify the claim. Support for the amendment to the fourth compound of claim 10 is found in the diagram on page 36 of the Specification, compound 44.

Claim 11 has been amended to be independent, and to clarify the claim.

Claim 12 has been amended to depend from claim 8, which is drawn to a compound, rather than a method.

Claim 15 is amended to recite “reperfusion after ischemia.” Support is found in the Specification at page 1, lines 24-25.

New claim 16 has been added. Support for claim 16 is found in claim 11, or in the Specification at page 13, lines 13-16.

New claim 17 has been added. Support for claim 17 is found in the Specification at page 12, lines 26-28.

No new matter has been added.

## **2. Rejections under 35 U.S.C. §§ 101 and 112**

The Examiner has rejected claims 1-7 and 15 for being in the improper “use” format. The Examiner states that “since the claim does not set forth any steps involved in the method/process claims, it is unclear what method/process applicant is intending to encompass.” Applicants have amended the claims thereby obviating the rejection. Applicants request that it be withdrawn.

## **3. Rejections under 35 U.S.C. §112, Indefiniteness**

The Examiner rejects claims 1, 7, 8, 14, and 15 as indefinite.

### *Claims 1, 7, & 8*

The Examiner states that the term “derivatives” in claims 1, 7, and 8, is indefinite because it includes isomers of formula (1) and, “isomers are only required to have the same elements and ratios thereof and therefore, may or may not resemble the depicted structure of formula (I).” Applicants have deleted the term derivative. Therefore, the rejection is obviated in view of this amendment. Applicants request that it be withdrawn.

### *Claims 1 & 8*

The Examiner rejects claims 1 and 8. The Examiner states that “[c]laims 1 & 8 recite the language “including” in the definition of Hy and the scope of this term is unclear.” Applicants have amended the claim, thereby obviating the rejection. Applicants request that the rejection be withdrawn.

### *Claims 14 & 15*

The Examiner rejects claims 14 and 15 for being indefinite, stating “There is no guidance to what is included or excluded from the term damages, nor is there any guidance as to determine

that the damages were in fact a result of ischemia or reperfusion.” (internal quotes omitted). Applicants point out that the terms “damages caused by ischemia and reperfusion” has been replaced with “damages caused by reperfusion after ischemia.” The term “and” in “damages caused by ischemia and reperfusion” was used to indicate consecutive events. Thus, “damages caused by ischemia and reperfusion” refers to damages that result from reperfusion subsequent to ischemia.

This is particularly clear in the Specification, page 1, lines 24-25. The damages deriving from reperfusion after ischemia are a well known and well characterized pathology, also called “reperfusion injury” as demonstrated by the attached Wikipedia reference. (Reference 1). Thus, Applicants submit that the claim language is clear in light of the teachings of the Specification, and request that the Examiner withdraw the indefiniteness rejection.

#### **4. Rejections under 35 U.S.C. §112, Written Description**

The Examiner rejects claims 1-9 and 11-15 as failing to meet the written description requirement. The Examiner states that “there are no working examples or synthetic procedures that would convey to one of skill in the art that Applicant had possession of compounds according to formula (I) wherein A is not equal to phenyl, pyrrole, indole, or 7-aza-indole.” Applicants respectfully traverse.

First, Applicants note that working examples are not required to meet the written description requirement. “An Applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams and formulas that fully set forth the claimed invention.” MPEP 2163 (I). The Examiner states that “[t]hose skilled in the art would recognize that all of the compounds characterized in the instant application are drawn to formula (I) wherein A= phenyl, pyrrole, indole, and 7-aza-indole, therefore such an element would be considered to be essential or critical to the utility of the products.” The Examiner’s statement is not supported by any scientific rationale and is merely conclusory. Moreover, his rationale is narrower than what is required for adequate written description. Applicants submit that they have adequately described

the claimed methods of treatment and compounds through the disclosure of words, structures, figures, diagrams and formulas and therefore meet the written description requirements.

Second, synthetic pathways to obtain the compounds of formula (I) wherein A is other than phenyl, pyrrole, indole or 7-aza-indole were well known in the art at the time the present application was filed. As shown by the enclosed references, these compounds could be made by the skilled artisan without undue experimentation. (These references are concurrently being entered by IDS for the Examiner's consideration.) Applicants provide a number of references showing the synthesis of derivatives containing such A groups, in particular:

A. Compounds where A is thiophene:

- i. Gronwitz et al (Reference 2)
- ii. Jackson et al (Reference 3)
- iii. US 2425721 (Reference 4)

B. Compounds where A is furane:

- i. Quesnelle et al (Reference 5)

C. Compounds where A is pyridine:

- i. Edgar et al (Reference 6)
- ii. Jones et al (Reference 7)
- iii. US 3883541 (Reference 8)
- iv. WO 0136415 (Reference 9)

D. Compounds where A is imidazole:

- i. WO 03013526 (Reference 10)

E. Compounds where A is naphthalene:

i. Buu-Hoi et al (Reference 11)

ii. Alam et al (Reference 12)

F. Compounds where A is pyrimidine:

i. Brown et al (Reference 13)

Thus, Applicants submit that the Specification and the knowledge in the art (as evidenced by the enclosed references) provided sufficient support for one of skill to understand that Applicants had possession of the claimed invention at the time of filing. Applicants request that the rejection be withdrawn.

#### **5. Rejections under 35 U.S.C. §112, Enablement**

The Examiner rejects claims 13-15 as not being enabled and states that “the specification, while enabling for a method of treatment of ischemia or reperfusion, does not reasonably provide enablement for prevention of ischemia or reperfusion.” Applicants respectfully traverse.

Applicants point out that the claim has been amended to recite “damages caused by reperfusion after ischemia.” The Examiner has already indicated that the Specification is enabling for a method of treatment of damages caused by reperfusion. Thus, Applicants submit that the present invention is enabled by the Specification.

#### **6. Claim Objections**

##### *Claims 7 & 10*

The Examiner objects to claims 7 and 10 because they lack commas. Applicants have amended claims 7 and 10 to add commas. Applicants request that the objection be withdrawn.

##### *Claim 8*

The Examiner objects to claim 8 for reciting “2-arylacetic acid compounds” because the structure is not an acetic acid. Applicants have deleted the term. Applicants request that the objection be withdrawn.

*Claim 10 Chemical Name*

Claim 10 is also objected because ChemDraw provides two alternatives for the compound listed as:

[1-methyl-5-(4-methylbenzoyl)-1H-pyrrol-2-yl]acetylmethanesulphonamide.

From the diagram on page 36 of the Specification, compound 44, Applicants submit that the proper structure is the second structure and the chemical name should be listed as:

[1-methyl-5-(4-methylbenzoyl)-1H-pyrrol-2-yl]acetyl methanesulphonamide. Applicants have amended the claim accordingly and request that the rejection be withdrawn.

*Claim 10 Independent*

The Examiner objects to claim 10 as being dependent on a rejected base claim, but which would otherwise be allowable. Applicants have amended claim 10 to delete the dependency. However, the Examiner also wishes to incorporate all the limitations of the prior claims. Since the four compounds meet the structural limitations of the previous claims, Applicants submit that making the claim independent is sufficient to overcome the Examiner's objection. Applicants respectfully request that the Examiner withdraw the rejection and allow claim 10 to proceed to allowance.

In view of the above amendment, Applicants believe the pending application is in condition for allowance.

**CONCLUSION**


Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), Applicant(s) respectfully petition(s) for a one (1) month extension of time for filing a reply in connection with the present application, and the PTO is authorized to charge payment of the required fee from Deposit Account No. 02-2448.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Mark J. Nuell Reg. No. 36,623 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

Dated: December 5, 2008

Respectfully submitted,

By 

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References: Refusion Injury (Reference 1)  
Gronwitz et al (Reference 2)  
Jackson et al (Reference 3)  
US 2425721 (Reference 4)  
Quesnelle et al (Reference 5)  
Edgar et al (Reference 6)  
Jones et al (Reference 7)  
US 3883541 (Reference 8)  
WO 0136415 (Reference 9)  
WO 03013526 (Reference 10)  
Buu-Hoi et al (Reference 11)  
Alam et al (Reference 12)  
Brown et al (Reference 13)